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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/588,553 06/07/00 FREYSSINET J P101614-0000

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HM12/1031

EXAMINER

GRUN, J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/31/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>09/588,553</b>	Applicant(s) <b>FREYSSINET et al.</b>
Examiner <b>James L. Grun, Ph.D.</b>	Art Unit <b>1641</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 17 Aug 2001

2a)  This action is **FINAL**. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 36-65 is/are pending in the application.

4a) Of the above, claim(s) 45-63 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 36-44, 64, and 65 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20)  Other: \_\_\_\_\_

Art Unit: 1641

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 17 August 2001 is acknowledged and has been entered. Claims 64-65 are newly added. Claims 36-65 remain in the case. Claims 45-63 have been withdrawn from further consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsperson will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

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Claims 36-44 and 64-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant teaches that an amount of circulating microparticles and/or stimulated procoagulant cells correlates with the prethrombotic state of a patient and correlates with the presence of various vascular diseases (see e.g. pages 6-7). However, there is no description or support for the method as is now claimed wherein a "prethrombotic state" is compared with "prethrombotic values" associated with an assortment of diseases and risk factors wherein a particular disease can be diagnosed or a particular risk factor identified. It is not clear what is encompassed by this step or how one performs the comparison as no description of this step can be found in the specification, as originally filed. Moreover, although the detection of an increased level of microparticles and/or stimulated procoagulant cells may be indicative of any of the various listed vascular diseases, it is not known or shown that any particular level is associated with any particular disease or risk factor. Absent any description or guidance from applicant, one would not be assured of the ability to practice the invention as is now claimed. Applicant is requested to direct the examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

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Claims 36-44 and 64-65 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 36-44 and 64-65, “the prethrombotic state”, “the diagnosis”, and “the amount” lack antecedent basis. It is not clear how determining complex relates to determining “the prethrombotic state”.

Claims 36-38, 41, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al (Thrombosis and Haemostasis 65: 467-473, 1991) in view of Rote et al (Clin. Immunol. Immunopathol. 66: 193-200, 1993) and Margel et al (J. Cell Sci. 56: 157-175, 1982) for reasons of record in the prior rejection of the similar subject matter of claims 36-38 and 41.

Claims 36-38, 41, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al (Thrombosis and Haemostasis 65: 467-473, 1991) in view of Rote et al (Clin. Immunol. Immunopathol. 66: 193-200, 1993) and Carriere (AU 22948/88) for reasons of record in the prior rejection of the similar subject matter of claims 36-38 and 41.

Claims 36-38, 41, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al (Thrombosis and Haemostasis 65: 467-473, 1991), in view of Rote et al (Clin. Immunol. Immunopathol. 66: 193-200, 1993), and further in view of Hajek et al (U.S. 5,340,719) and/or Harlow et al for reasons of record in the prior rejection of the similar subject matter of claims 36-38 and 41.

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With regard to the above paragraphs, in addition to the teachings of Abrams et al set forth previously, the reference teaches the use of the method of detection of activated platelets and platelet-derived microparticles for diagnostic identification of certain thrombotic disorders and evaluation of therapeutic strategies (e.g. page 467). The pattern of surface activation in different clinical situations is likely to be different and should be determined (i.e. comparisons between different clinical situations should be made) (e.g. page 471).

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al in view of Rote et al and Margel et al, and further in view of Dachary-Prigent et al (Blood 81: 2554-2565, 15 May 1993) for reasons of record.

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al in view of Rote et al and Carriere, and further in view of Dachary-Prigent et al (Blood 81: 2554-2565, 15 May 1993) for reasons of record.

Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al, in view of Rote et al, Hajek et al ('719), and/or Harlow et al, and further in view of Dachary-Prigent et al (Blood 81: 2554-2565, 15 May 1993) for reasons of record.

Applicant's arguments filed 17 August 2001 have been fully considered but they are not deemed to be persuasive. Applicant urges that the references do not teach comparisons as are now claimed. This is not found persuasive in view of the additional teachings of the reference of Abrams et al, noted above, now incorporated into the reasons for rejection.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, applicant urges that Dachary-Prigent et al do not teach determinations of platelets activated *in vivo*. This is not found persuasive because the use of the method for determination of platelets activated *in vivo* is clearly found in the reasons of record, particularly in the teachings of the primary reference of Abrams et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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This application contains claims 45-63 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

*JL*  
James L. Grun, Ph.D.  
October 30, 2001

*Christopher L. Chin*  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 / 1641